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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,532	12/12/2001	Roberto Villa	9623 V/vmf/as	4029

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,532	VILLA ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 20-24* is/are pending in the application.

4a) Of the above claim(s) *21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment after Non-Final Office Action, Applicant's Argument/Remarks and the request for extension of time (1 month-granted), all filed 10/03/05 is acknowledged.

Newly submitted claims 21-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submitted claims 21-24 are drawn to a composition that requires an active ingredient incorporated in a three-component homogeneous matrix structure whereas the originally filed claims are drawn to a composition that does not require a three-component homogeneous matrix structure as claimed. Originally filed claims 1-14 and 20 entail a composition wherein each system (lipophilic matrix/drug; amphilic matrix/drug; hydrophilic matrix) can be formulated separately and then combined to form one single composition whereas newly submitted claims 21-24 entail a composition formulated by combining all of the components (lipophilic matrix/drug; amphilic matrix/drug; hydrophilic matrix) in combination, rather than individually or separately. Thus, newly submitted claims 21-24 are distinct from the invention originally claimed.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claims 21-24 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The claim objection for claim 11 (typographical error) as well as the objection to specification (pg. 6-typographical error) has been withdrawn, by virtue of Applicant's amendment.

Claims 1-14 and 20 are pending in this action. Claims 21-24 have been withdrawn. Claims 15-19 have been cancelled. Claims 1-14 and 20 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama *et al.* (EP 0 514 008 A1).

Akiyama *et al.* teach a gastrointestinal mucosa-adherent matrix comprising a viscogenic agent, a matrix containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient and enteric polymers (see p. 2, line 55 to p. 3, line 7). Akiyama *et al.* teach viscogenic agents, such as polymers containing carboxyl groups or salts thereof, such as acrylic acid polymers, cellulose ethers, such as carboxymethylcellulose sodium, hydroxypropylmethylcellulose, methylcellulose, polyethylene glycols and naturally occurring mucous substances, such as pectin, carrageenan, gums, alginate and waxes, among the viscogenic agents used in the invention (p. 3, lines 23-56).

Akiyama *et al.* teach fatty acids that include, for example, saturated or unsaturated higher fatty acids containing 8-40, preferably 12-22 carbon atoms. Lipids are taught as a constituent of the matrix and have a melting point of 40-120°C, preferably 40-90°C, (p. 4, line 20 to p. 5, line 6). Typical examples of lipids include, for example, saturated fatty acids containing 14 to 22 carbon atoms, and salts thereof, higher alcohols containing 16 to 22 carbon atoms, glycerol fatty acid esters, oils, waxes, hydrocarbons, phospholipids and so on (p. 4, line 20 to p. 5, line 6).

Akiyama *et al.* contemplate a great variety of active ingredients, which can be delivered using the system of the invention, including analgesics, hypnotics and sedatives, psychotropic agents, bronchodilators and antitussives (p. 5, lines 7-15). Specific examples of the active ingredient include ketoprofen, ibuprofen and isosorbide dinitrate, for example (p. 5, lines 18-29).

Akiyama *et al.* teach that the composition may comprise an enteric polymer, such as Eudragit, and various additives (p. 7, lines 2-39). Akiyama *et al.* teach that the viscogenic agent is dispersed in the surface layer of the matrix containing the active ingredient and the lipid, or the matrix may be coated with a coating composition comprising the viscogenic agent (p. 7, lines 42-45). Thus, the art contemplates an outer hydrophilic matrix, as claimed by Applicant. Akiyama *et al.* teach that granules may be manufactured from the matrix (p. 8, lines 44-53).

According to Akiyama *et al.* the preparations of the invention may be provided in various dosage forms, including pills, tablets and capsules (p. 10, lines 12-21). With regards to Applicant's phrase limitation 'chewable or erodible in the buccal cavity' in instant claim 14, the Examiner notes that the phrase 'chewable or erodible' denotes a future-intended use limitation, which affords no significant patentable weight to the claim.

Additives are taught in the composition and include various excipients, such as, for example, lactose, cornstarch, talc, crystalline cellulose, binders such as methylcellulose, carboxymethylcellulose, surfactants, gastric antacids and mucosa-protecting agents, colorants, adsorbents, preservatives, disintegrating agents and so on (p. 7, line 57 to p. 8, line 13).

The examples at pages 10-18 demonstrate various embodiments of the invention.

Akiyama *et al.* provide controlled release compositions and dosage forms, as claimed. Akiyama *et al.* do not specifically mention that the compositions of the invention are taste-masking, however, the patent teaches and recognizes the same general categories of active ingredients and excipients as claimed in the instant application and thus the same properties and results would be expected, including the 'taste-masking' property desired by Applicant. Burden is shifted to Applicant to show that the compositions disclosed by the prior art would not be capable of masking the unpleasant taste of certain drugs.

According to Akiyama *et al.*, controlled-release drug delivery systems are advantageous in that they help reduce frequency of administration of a drug, prevent sudden elevation of blood-drug concentrations and they help maintain therapeutically effective blood concentration levels for an extended period of time (p. 2, lines 9-17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the teachings of Akiyama *et al.* to formulate controlled release pharmaceutical compositions for the delivery of drugs in the gastrointestinal tract. The expected result would be a successful controlled release pharmaceutical composition. Because of the teachings of Akiyama *et al.*, that a variety of active agents can be delivered by the compositions of the invention, one of ordinary skill in the art would have a reasonable expectation that the

compositions claimed in the instant application would be successful. Therefore, given the teachings of Akiyama *et al.*, the instant invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Prior Art made of record, not relied upon and deemed relevant by Examiner:

US Patent No. 6,368,635 B1 (Akiyama et al.) (04-2002)

- Akiyama *et al.* teach a matrix composition comprising a viscogenic agent dispersed on the surface layer of a matrix particle containing a polyglycerol fatty acid ester or a lipid and an active ingredient. The matrix may be such that a matrix particle containing a polyglycerol fatty acid ester or a lipid and an active ingredient has been coated with a coating composition containing at least one viscogenic agent. The composition can remain in the digestive tract for a prolonged period of time, thereby increasing bioavailability of the active ingredient (see Abstract).

Response to Arguments

Applicant's arguments filed 10/03/05 have been fully considered.

Firstly, Applicant responded in regards to the claim and specification objections stating, "The present specification and claims have been amended to address these objections". Accordingly, the claim and specification objections have been withdrawn, by virtue of Applicant's amendment.

Secondly, Applicant argued regarding the 35 U.S.C. §103 (a) rejection over claims 1-14 and 20 over Akiyama et al. (EP 0514008) stating, "The claimed invention is distinct from the stratified reservoir structure taught by Akiyama et al. Akiyama et al. fails to disclose or suggest the claimed invention."

Applicant's arguments have been fully considered, but they were not found persuasive. Akiyama et al. teach a gastrointestinal mucosa-adherent matrix comprising a viscogenic agent, a matrix containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient and enteric polymers. The matrix system taught by Akiyama et al. provides for a controlled release composition, which contains similar ingredients as instantly claimed. While the patentability of the composition needs to be established, it is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results, which accrue from the instant homogeneous matrix structured composition as claimed. The prior art initially teaches and is directed to a composition that comprises identical components (lipophilic, amphiphilic, hydrophilic substances), used for the same field of endeavor as desired by Applicants. Therefore, it is the position of the Examiner, that given the teachings of Akiyama et al. to formulate controlled release pharmaceutical compositions for the delivery of drugs using a variety of components, such as viscogenic agents, lipids, etc. in a matrix system used in the gastrointestinal tract, the instant invention, when taken as a whole would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh

Patent Examiner

Art Unit 1615

January 05, 2006

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